PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Health assessment of commercial drivers: A Meta-narrative Systematic Review
AUTHORS	Abu Dabrh, Abd Moain; Firwana, Belal; Cowl, Clayton; Steinkraus, Lawrence; Prokop, Larry; Murad, M. Hassan

VERSION 1 - REVIEW

REVIEWER	Hartenbaum, Natalie OccuMedix
REVIEW RETURNED	14-Jul-2013

GENERAL COMMENTS	poorly wordend, seems to mix what they are trying to explain. I would not recommend publishing this in the current form and would NOT want my name associated with the article if accepted. Would be willing to review again if better organized. Should not draw conclusion on an issue from a single study and then call this a meta-analysis - actually just reporting findings from 1-3 studies on a specific condition

- The reviewer also provided a marked PDF copy with further comments. This can be available upon request to the Publisher.

REVIEWER	Marta Marino, MD Legal and Forensic & Hygiene and Preventive Medicine specialist National Observatory on Health in the Italian Regions Institute of Public Health - section of Hygiene Università Cattolica del Sacro Cuore - Teaching Hospital "A. Gemelli", Rome
REVIEW RETURNED	16-Aug-2013

GENERAL COMMENTS	STUDY DESIGN: - Meta-narrative review is a new approach to systematic review. RAMESES publication highlight standards to report meta-narrative review findings. The authors do not use the term "meta-narrative review" in the introduction and methods (the review is defined "systematic"), but they justify the use of such an approach with the "methodological heterogeneity between studies" included. Meta-narrative review, as reported in RAMESES publication, has got some standards that can be identified in this article, e.g. the presence of the name "meta-narrative" in the title, the rationale for the review, the study of the problem by different approach (clinical,

	economical...). A rationale for using the meta-narrative approach is not a clear from the beginning: the authors do not explain they are using such an approach, for example, because of the extent of the problem, the different literatures exploring the topic, the broad range of sources, the different poin of view or the complex topic area. It seems the whole review was conducted as a systematic review from the beginning (scope and methods), changing into a meta-narrative systematic review after the selection of the included studies, in order to describe the heterogeneus results, instead of illuminate a complex area from multiples angles. INTRODUCTION: - Add the acronim "FMCSA" at page 7 line 38 - erase bracket page 7 line 52 METHODS: - I could not find the "search terms" the authors looked for searching the databases, the overall search strategy by using mesh terms and key words. The literature search is not defined "systematic" but "comprehensive" - in my opinion inclusion criteria are not so clear and exclusion criteria are not reported at each stage (see figure 2). It's not possible to see how many papers came out from each consulted database - Table 1 describe the included studies in chronological order. In my opinion an order referred to clinical condition and economic aspect could be easier to read, dividing OSAS studies from diabetes, from alcohol, economic and so on (e.g. table 2). It should be better to add a legend for the acronym and semplify the clinical condition description. RESULTS: - Figure 2, it's not reported the reason for exclusion of 98 citations in the first step - I would add the references at page 12, when describing medical conditions, and would move the descrition of economic studies ("three economic studies and cost effectiveness in different conditions in commercial drivers") at the end of the clinical condition, not leaving it in-beetween. DISCUSSION AND CONCLUSION: - In the first line the authors still describe the review as systematic and not meta-narrative (thir term is not found in the discussion section) - limitations are clear if referred to the findings, but no limitations referring to the methodology of the review proces are listed - Page 7, line 38: add the acronym FMCSA, that is cited below but not explained above. - Page 7 line 52: erase the bracket after the word "condition" - Table 1 "description of included studies": I would make more clear the clinical condition analized by each of the reference, and probably I will order the references by clinical conditions and economic study at the end, in order to facilitate the reading - Tables: I would add a Legend for the cited acronyms

VERSION 1 – AUTHOR RESPONSE

• Reviewer 1: Natalie P. Hartenbaum, MD, MPH

o Dr. Hartenbaum's comments were sent as PDF embedded comments and are pasted below with response:

The first three comments diagnosis:
What does this mean? paucity of evidence to diagnosis? I think you mean The current evidence is insufficient to recommend diagnostic strategies specific for many medical diagnosis to determine the medical fitness of commercial drivers. The diagnosis of the medical condition is not the issue - the challenge is how to evaluate the medical fitness for a given diagnosis. Not sure you can draw this conclusion from the data reviewed and presented
Authors' response: We agree. We revised the sections pertaining to the diagnostic strategies using the reviewer's suggested verbiage.

• poorly worded
Authors' response: Edits made

• please cite your reference
Authors' response: Thank you. Reference is added and updated.

• associated with a crash or with crash risk?
Authors' response: Sentence reworded.

• not resulted - may have been found in drivers with
Authors' response: We agree, sentence reworded.

• poorly worded
Authors' response: We agree, reworded.

• is this health assessment or fitness for duty?

Authors' response: We revised text to clarify that we are evaluating the fitness to drive assessment.

• have you looked at the reviews from the FMCSA medical expert panels - they looked at both commercial and non-commercial drivers

Authors' response: We have looked at these documents and even cited several of them. Please note however that we are only including studies done exclusively in commercial drivers.

• health performance?? poorly worded

Authors' response: Sentence clarified; thank you.

• with this many dissimilar characteristics are you really combining data or just evaluating each individually

Authors' response: We are actually evaluating a body of evidence. The meta-narrative approach involves identifying key data elements defined a priori and extracted from individual studies but summarized as a whole. For example, from several individual studies we isolated a certain condition (e.g., sleep apnea) and its prevalence (presented as a range) and association with crashes (presented as odds ratio). Of course, on occasions there was a single study that answered a particular question. The methods section is re-written for better clarification.

• this does not flow - talking about sleep disorders, then OSAS, then DM with a crash risk and then BMI??? Not well organized

Authors' response: The way we organized the report is by following the analytic framework figure (figure 1). Therefore, we started by prevalence, then risk of crashes, diagnostics and economic studies. In each section, you have multiple diseases. We opted to not divide the report per condition or disease because our goal is to evaluate the fitness to drive exam as a whole from these angles, and we did not aim at providing data per disease.

• is this only one study? not consistent with some other reports

Authors' response: Yes. The reference is cited at the end of the sentence.

• is this also reference 19?

Authors' response: This is reference 21 and followed by evidence from the same study. citations corrected and verified.

• perhaps in this study but others have found otherwise

Authors' response: This is what was reported in the eligible study. In addition, another study (Gjerde et al (reference No. 44) also found that levels of psychoactive drugs were lower among commercial drivers in comparison to noncommercial drivers.
We would like to know of other studies that reported that to see if they are eligible for our review. This is of course not to say that this problem is not evident among commercial drivers but rather to outline it is under-reported.

• these did not evaluate abnormal sleep but sleepiness or risk for OSA

Authors' response: We changed this to sleep disorders
• what consensus criteria - Do you mean the Tri-Medical Society from JOEM 2006 - if so should reference

Authors' response: The criteria have been referenced.

• this is considered gold standard for evaluating sleep disorders so should not say less commonly used.

Authors' response: What you are stating is right in general practice but here, we are reporting what these studies have used for this type of population. Most studies actually relied on using scales rather than the "gold standard" tests because they are not used as a standard tool to screen for fitness-to-drive due to various reasons (e.g. insurance coverage, convenience).

• I believe this was Operation Downshift and sponsored by a pharma company but did it have a relationship to crash or just passing the exam. in other parts of paper discussed crash -need to choose an endpoint you are evaluating

Authors' response: The program is a free web-based tool sponsored by Novartis. To be clear, this tool was developed to help drivers maintain an active driving status. The value of this is to report that using certain strategies (in this case, the Downshfit program) when after screening and diagnosing drivers with hypertension was helpful in treatment adherence and minimizing disqualification based on fitness-to-drive evaluation. In the other part in the manuscript (economic impact in the results section), we did not link the Downshift program to risk of crashes but rather its effect in minimizing cost. These are two distinctive valid endpoints.

• strategy? diagnostic studies - how about a good history and physical examination?

Authors' response: We agree about the importance of history and physical examination. However, we are describing the diagnostic strategies reported in these studies.

• if this is true, please reference as I do question this statement - part of the assessment of cost needs to consider the criteria used to determine who needs to be tested.

Authors' response: This is referenced under citation # 38
as noted here.

• health care cost savings?

Authors' response: Yes. As stated in the prior sentence. This also means it is cost-saving to the hiring companies.

• one study, cannot generalize and was this a high quality study?

Authors' response: We added a sentence highlighting that these data are from a single study.

• this is a statement but does not flow from earlier comments

Authors' response: This is the last economic analysis study and these are its main conclusions.

• more severe? more fatalities involved, higher economic burden? more frequent?

Authors' response: Thank you for making this point. Mainly more fatalities. Sentence clarified.

• why state this??

Authors' response: Sentence removed.

• the paucity is the relationship between the condition and crash risk and the best way to evaluate which drivers are safe with a given condition and which are not.

Authors' response: We agree and this sentence added.

• are you looking at just CMV operators or all drivers??

Authors' response: We are only including studies in commercial drivers. This reference (which is about the general population) is cited in the discussion and is not one included in the systematic review.

• Comment (?????) about citation numbering.

Authors' response: Our numbering is correct. This (number 50) is a continuation of citation from previous line.

o Comment : Should not draw conclusion on an issue from a single study and then call this a meta-analysis - actually just reporting findings from 1-3 studies on a specific condition.

Authors' response: We would like to point out that this is not a meta-analysis. This is a systematic review. We have actually summarized 32 studies. In some questions or sub-questions, there was a small number of studies. This is the status of the existing evidence.

• Reviewer: Marta Marino, MD

Legal and Forensic & Hygiene and Preventive Medicine specialist National Observatory on Health in the Italian Regions Institute of Public Health - section of Hygiene Università Cattolica del Sacro Cuore - Teaching Hospital "A. Gemelli", Rome

I have read and understood the BMJ Group policy on declaration of interests and declare the following interests: none.

STUDY DESIGN:
- Meta-narrative review is a new approach to systematic review. RAMESES publication highlight standards to report meta-narrative review findings.
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A rationale for using the meta-narrative approach is not a clear from the beginning: the authors do not explain they are using such an approach, for example, because of the extent of the problem, the different literatures exploring the topic, the broad range of sources, the different poin of view or the complex topic area. It seems the whole review was conducted as a systematic review from the beginning (scope and methods), changing into a meta-narrative systematic review after the selection of the included studies, in order to describe the heterogeneus results, instead of illuminate a complex area from multiples angles.

Authors' response:
We thank you for raising up this point. Though the title provides a self-description of the type of systematic reviews we are using here (Meta-narrative), we agree that it would make it clearer for the readers to mention that in the introduction as well and replace the terms systematic review with metanarrative review across the board. We have added to the manuscript what reflect these changes. (Page 7, data synthesis)

As for the whether to if we started with a systematic review from the beginning or not, we disagree with Dr. Marino. We want to point out, as clearly explained in the methods section, that we pursued this metanarrative approach after we thoroughly searched the literature and found extensive heterogeneity in the literature and complexity of the topic which warranted this approach instead of pursuing a meta-analysis approach. It is customary to evaluate

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INTRODUCTION:
- Add the acronim "FMCSA" at page 7 line 38
- erase bracket page 7 line 52
Authors' response:
Both have been edited.

METHODS:
1. I could not find the "search terms" the authors looked for searching the databases, the overall search strategy by using mesh terms and key words. The literature search is not defined "systematic" but "comprehensive"
2. in my opinion inclusion criteria are not so clear and exclusion criteria are not reported at each stage (see figure 2). It's not possible to see how many papers came out from each consulted database
3. Table 1 describe the included studies in chronological order. In my opinion an order referred to clinical condition and economic aspect could be easier to read, dividing OSAS studies from diabetes, from alcohol, economic and so on (e.g. table 2). It should be better to add a legend for the acronym and semplify the clinical condition description.

Authors' response:

1. The key words are listed in the title/authors page under words count (Page 5/41 line 53).
2. Literature search and study eligibility section (Page 9/41) details the inclusion criteria. Any studies that did not meet those criteria were excluded.
3. Certainly a good idea. However, due to the fact that certain studies reported more than one outcome of interest or medical condition, we opted to outline the studies in chronological order.

RESULTS:
1. Figure 2, it's not reported the reason for exclusion of 98 citations in the first step
2. I would add the references at page 12, when describing medical conditions, and would move the descrition of economic studies ("three economic studies and cost effectiveness in different conditions in commercial drivers") at the end of the clinical condition, not leaving it in-beetween.

Authors' response:
1. That's an initial screening, which usually means that studies that were not related to the scope of interest or the "PICO" criteria are excluded on abstracts level.
2. We agree about reordering. Edits were made. The references are reported later based on the conditions and scope of question. We felt that it might crowd the manuscript and confuse the readers.

DISCUSSION AND CONCLUSION:
1. In the first line the authors still describe the review as systematic and not meta-narrative (thir term is not found in the discussion section)
2. limitations are clear if referred to the findings, but no limitations referring to the methodology of the review proces are listed

3. Page 7, line 38: add the acronym FMCSA, that is cited below but not explained above.
4. Page 7 line 52: erase the bracket after the word "condition"
5. Table 1 "description of included studies": I would make more clear the clinical condition analized by each of the reference, and probably I will order the references by clinical conditions and economic study at the end, in order to facilitate the reading
6. Tables: I would add a Legend for the cited acronyms

Authors' response:
1. That has been edited
2. We added a paragraph on the limitations of the review.
3. This has been addressed earlier
4. This has been addressed earlier
5. This has been addressed earlier
6. Thank you for the suggestion. A legend has been added to the table as recommended.

VERSION 2 – REVIEW

REVIEWER	Hartenbaum, Natalie OccuMedix
REVIEW RETURNED	23-Oct-2013

GENERAL COMMENTS	This article still does not seem to show a understanding of the medical certifications process of commercial drivers in the US or other countries. Does not address that there are medical standards and criteria for performing the examinations. Several areas that just don't follow. I would suggest a major rewrite but in the end, it states it looks at diagnostic strategies but does not discuss any except for OSA and mentions cost but only a few studies which could be included in their analysis.

- The reviewer also provided a marked PDF copy with further comments. This can be available upon request to the Publisher.

VERSION 2 – AUTHOR RESPONSE

• Reviewer 1: Natalie P. Hartenbaum, MD, MPH

o Dr Hartenbaum's comments were sent as PDF embedded comments and are pasted below with response in the PDF's corresponding order:

ABSTRACT COMMENTS

1. no one refers to these as CDMLE, generally CDME or inaccurately DOT examination.
Authors Response: The abbreviation is changed as suggested, thank you.

2. please reference this, it is inaccurate - motor vehicle accidents is the leading cause, NOT CMV operations
We clarified the sentence in the abstract and added citation in the introduction.

3. your background should include what you are exploring - nothing here mentions medical
Authors Response: We edited the objective section in the manuscript to reflect reviewer's suggestion.

4. no, you looked at the relationship between medical conditions and commercial drivers but there are many conditions where there are no reviews.
Authors Response: We agree. The abstract now includes that several relevant conditions have not been studied.

5. the rationale is that it is required by federal law.
Authors Response: Our review provides a scientific rationale for the exam. The fact that there are prevalent conditions in commercial drivers that have significant implications, justifies the exam. You are correct that it is mandated. This is mentioned in the introduction, second paragraph.

6. reference?
Authors Response: It is not recommended to use references in abstracts.

7. what does this mean? what diagnostic strategiesare you referring to? stress testing? CT scans? Not going to be looked at in relation to CMDE as would be normal medical practice
Authors Response: Sentence deleted.

STRENGTHS AND LIMITATIONS OF THIS STUDY COMMENTS

8. not what you are doing - you are looking at the relationship between medical conditions and commercial drivers. Did you look at the GAO report on medical certifications and commercial drivers who the reports from NTSB
Authors Response: Sentence changed as suggested.

9. when you say different classes, do you mean truck and bus, inter and intra state. these differences may result in differences in crash risk
Authors Response: The studies included multiple commercial vehicle types. Sentence deleted nevertheless.

INTRODUCTION SECTION COMMENTS

10. not necessarily true - in the US, a medical examination is required for many drivers that do not need CDL - vehicles between 10,000 and 26,000 pounds for example.
Authors Response: Correct but we want to point out that we are just providing a general definition of commercial vehicle drivers. We are not defining who only qualifies or not for CDME.

11. is this commercial driving or motor vehicle accidents
Authors Response: We made edits to better reflect

12. poor wording - and is this just OSA
Authors Response: Edits made

13. not necessarily diagnostic - just evaluation
Authors Response: Edits made

14. is this the correct reference - Akerstadt? Fatigue and it is from 2000
Authors Response: The reference is correct to give an example of one of the conditions but was re-positioned later in the sentence. Edits made

15. have you looked at more recent prevelance data
Authors Response: Yes but we found the references to be representative of current estimates and still widely reported in recent studies.

16. hypertension from the 5 years of MRB - not a significant concern and not one that the MRB spent a lot of time on.
Authors Response: The medical review board may not be concerned about hypertension. Yet, we are summarizing the litearure to the best of our ability and this is how it is reported in the studies.

17. this is not commercial drivers but those whose fitness is more questionable than those who appear generally healthy as most drivers appear.
Authors Response: Agreed. We referenced this review as an example of a systematic review conducted in drivers from the general population, not for commercial drivers. We only used the word drivers here. The first line of the paragraph also points out that this assessed fitness-to-drive among drivers in general population.

18. just because the conditions were found in drivers with crashes does not mean the conditions are causal. common conditions will be found commonly
Authors Response: We agree. Across the whole manuscript we used the word “association”.

19. appraise???
Authors Response: Appraise as in appraise the evidence, a general term used to denote the benefit of conducting systematic reviews.

RESULTS SECTION COMMENTS

20. fitness to drive is diferent than performing duties of the commercial motor vehicle operator in the US. In the US, terms such as DOT examiner, CDME are used
Authors Response: We agree but we included non US studies and therefore used the term fitness to drive instead of US specific terms such as DOT and CDME.

21. so VERY heavy on OSA with only 13 articles that looked at other conditions. Do you think that is sufficient to recommend what should be done in a medical certification examination.
Authors Response: In systematic reviews we aim at summarizing and appraising the evidence and try to not make recommendations. The studies relating to OSA are the most, so we are just reporting what we found.

22. where is your reference on this
Authors Response: This is a mean from the group of studies in table 2. In the revised manuscript we added reference to table after the sentence and added the word”mean”

23. not true - they can get an exemption for interstate driving, possibly for intrastate and for school bus drivers depends on state
Authors Response: Correct. Edits made and this was clarified in the discussion section.

24. probably did not find as drivers with seizures are in generally not able to be certifed and recommended tht drivers with CKD should also not be.
Authors Response: We agree. In the discussions section, we discuss possible reasons for not finding such studies.

25. I think your references are off. 21 is on OSA
Authors Response: The study had a population of OSA and other co-existing conditions, including DM. The study concluded increased risk in the DM subgroup.

26. this is on diabetes
Authors Response: Same as question 25. The study had a population of multiple comorbidities, including DM and hypertension. The study concluded increased risk in the HTN subgroup.

27. yes there is a relationship between illicit drug use as well as between abuse of licit medications. You may not have found as with drug testing has limited how common this may be found
Authors Response: We agree. In the discussions section, we discuss possible reasons for not finding such studies.

28. this was not a diagnostic strategy but a programs by a pharmaceutical company encouraging drivers to get BP controlled when the BP guidelines changes
Authors Response: The program included a screening component for BP and led to new diagnoses of hypertension; therefore, we mentioned it in the diagnosis section.

29. what screening aside from drug testing?
Authors Response: This meant to reflect different methods (e.g. blood, urine, hair analysis…etc.)

30. This is important - you would use the same diagnositc tools as in the general population but the key is identifying those drivers at risk who need the additional studies.
Authors Response: Thank you. These findings also agree with your statement.

31. you would never SCREEN with polysomnogram but would determine which drivers need diagnostic study
Authors Response: We are in total agreement with you. This is what we said:
"Screening for OSAS in commercial drivers using polysomnography was found to not be cost-effective (more expensive than the cost of crashes when no screening is done). However, a stratification approach using BMI, age and gender with subsequent confirmatory in-lab polysomnography for high-risk drivers was cost-effective if 74% of those diagnosed accepted treatment (42). "

32. there was a study looking at improving overall health of drivers several years ago. you are only assume a saving if drivers loose weight - no real screening is necessary to check weight and calculate BMI.
Authors Response: We agree and the sentence is consistent with your suggestion:
"….. suggesting possible cost saving if screening and management of obesity lead to reduction in the incidence of obesity complications."

33. how does this relate - earlier stated no relationship with alcohol
Authors Response: This section summarized the economic impact. This study didn't examine the association between alcohol and crashes; the study reviewed claims of drivers who were involved in alcohol-related crashes and estimated the economic impact.

DISCUSSION SECTION COMMENTS

34. are they more prevelent than in the general populations? if so by how much?
Authors Response: Sentence clarified; thank you.

35. nothing in the body of your article addesses this nor do you explain how you reached this conclusion
Authors Response: In this part of the discussion, we are summarizing what is found in the relevant literature in general, and not specifically to our studies only.

36. same as reference 8
Authors Response: Reference updated.